IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
INTELLIPHARMACEUTICS INTERNATIONAL INC., INTELLIPHARMACEUTICS CORPORATION, and INTELLIPHARMACEUTICS LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P. ("Purdue Pharma") and Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") (collectively, "Purdue"), Rhodes Technologies ("Rhodes"), and Grünenthal GmbH ("Grünenthal") (collectively, "Plaintiffs"), for their Complaint against Intellipharmaceutics International Inc., Intellipharmaceutics Corporation, and Intellipharmaceutics Ltd. (collectively, "Intellipharmaceutics" or "Defendants"), aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 10,407,434 (the "'434 patent") and 10,369,109 (the "'109 patent") (collectively, "the patents-in-suit"). This action relates to New Drug Application ("NDA") No. 209653 ("Defendants' NDA"), including all amendments and supplements thereto, submitted in the name of Intellipharmaceutics to the United States Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendants have infringed the patents-in-suit. The patents-in-suit are listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering Purdue's OxyContin® (oxycodone hydrochloride) ("OxyContin®"), an extended-release pain medication. Defendants have infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by filing NDA No. 209653, submitted in the name of Intellipharmaceutics to the FDA. Defendants' NDA references Purdue's OxyContin®, which is the subject of approved NDA No. 022272, and seeks approval to market an extended-release oxycodone product in 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg dosage strengths ("Defendants' NDA Products").

3. Plaintiffs file their Complaint in response to Defendants' letter dated March 12, 2020, addressed to Plaintiffs and received by Purdue Pharma on or about March 17, 2020, in which Defendants provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' NDA, Defendants' NDA Products, and the patents-in-suit, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

THE PARTIES

4. Plaintiff Purdue Pharma is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the '434 patent, identified in paragraph 37 below, and Purdue Pharma is an exclusive licensee of the '109 patent, identified in paragraph 38 below. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

5. Plaintiff Purdue Pharmaceuticals is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the '434 patent, identified in paragraph 37 below.

6. Plaintiff Rhodes is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the '434 patent, identified in paragraph 37 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

7. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstrasse 6, Germany. Grünenthal is the owner of the '109 patent, identified in paragraph 38 below.

8. On information and belief, Intellipharmaceutics International Inc. ("IPC International") is a Canadian corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC International is in the business of making and selling pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On information and belief, IPC International owns, directly or through its wholly owned subsidiary Intellipharmaceutics Ltd. ("IPC Ltd."), 100.00% of the common shares of Intellipharmaceutics Corporation ("IPC Corp.").

9. On information and belief, IPC Ltd. is a Delaware Corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC Ltd. is a wholly owned subsidiary of IPC International and is controlled and/or dominated by IPC International. On information and belief, IPC Ltd., with the assistance and/or direction of IPC International and/or IPC Corp., develops, manufactures,

markets, offers to sell, and sells drug products for sale and use in the state of Delaware and throughout the United States.

10. On information and belief, IPC Corp. is a Canadian corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC International owns, directly or through its wholly owned subsidiary IPC Ltd., 100.0% of the common shares of IPC Corp. On information and belief, IPC Corp. is the operating affiliate of IPC Ltd. On information and belief, IPC Corp., with the assistance and/or direction of IPC International and/or IPC Ltd., develops, manufactures, markets, offers to sell, and sells drug products for sale and use in the State of Delaware and throughout the United States.

11. On information and belief, IPC Corp. is controlled and/or dominated by IPC International. On information and belief, IPC International operates through its wholly owned subsidiary and agent, IPC Ltd.

12. On information and belief, IPC Ltd., IPC Corp., and IPC International have common officers and directors and have represented to the public that they are a unitary entity.

13. On information and belief, the acts of IPC Corp. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, IPC Ltd. and/or IPC International.

14. On information and belief, the acts of IPC Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, IPC Corp. and/or IPC International.

15. On information and belief, the acts of IPC International complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, IPC Corp. and/or IPC Ltd.

SUBJECT MATTER JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

19. On information and belief, IPC Corp. and IPC Ltd. have previously been sued in this district and have not challenged and/or agreed to venue. *See, e.g., Purdue Pharma L.P. v. Intellipharmaceutics Corp.* (D. Del. C.A. No. 17-392-RGA); *Purdue Pharma L.P. v. Intellipharmaceutics Corp.* (D. Del. C.A. No. 18-404-RGA).

PERSONAL JURISDICTION

20. On information and belief, IPC International, IPC Corp. and IPC Ltd. are in the business of formulating, manufacturing and commercializing pharmaceutical products.

21. On information and belief, IPC International, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops drug products for sale and use throughout the United States, including within this judicial district.

22. On information and belief, IPC Corp., with the assistance and/or at the direction of IPC Ltd. and/or IPC International, develops drug products for sale and use throughout the United States, including within this judicial district.

23. On information and belief, IPC Ltd., with the assistance and/or at the direction of IPC Corp. and/or IPC International, develops drug products for sale and use throughout the United States, including within this judicial district.

24. On information and belief, IPC International, IPC Corp. and IPC Ltd. operate as an integrated, unitary business.

25. On information and belief, IPC Ltd., through IPC Corp., develops controlled-release pharmaceutical products, and licenses these developed products for commercialization.

26. On information and belief, IPC International, IPC Corp. and IPC Ltd. acted in concert to develop Defendants' NDA Products, and to seek approval from the FDA to sell Defendants' NDA Products throughout the United States and in this judicial district.

27. On information and belief, IPC International and/or IPC Ltd., through their authorized agent and subsidiary, IPC Corp., submitted NDA No. 209653 to the FDA. On information and belief, IPC International and IPC Ltd. have attributed the acts of IPC Corp. to themselves. On information and belief, IPC International, IPC Ltd. and IPC Corp. thus acted as a single entity in connection with preparing and submission of NDA No. 209653. On further information and belief, IPC Corp. acted as an agent of IPC International and/or IPC Ltd.

28. On information and belief, and as previously noted, IPC Ltd. is a corporation organized and existing under the laws of Delaware. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over IPC Ltd.

29. On information and belief, by virtue of, *inter alia,* IPC Ltd.'s relationship with IPC International in connection with the preparation and/or filing of NDA No. 209653, and their systematic and continuous activities in Delaware, including but not limited to the

development of drug products for sale to residents of Delaware, this Court has personal jurisdiction over IPC International.

30. On information and belief, by virtue of, *inter alia*, IPC Ltd.'s relationship with IPC Corp. in connection with the preparation and/or filing of NDA No. 209653, and their systematic and continuous activities in Delaware, including but not limited to the development of drug products for sale to residents of Delaware, this Court has personal jurisdiction over IPC Corp.

31. On information and belief, separate and apart from its relationship with IPC Ltd., IPC International has availed itself of the laws of the State of Delaware and engaged in a course of conduct in the State of Delaware, at least by incorporating and/or maintaining the incorporation of its subsidiary and/or agent IPC Ltd. under Delaware law, and identifying the Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, as the registered agent of IPC Ltd.

32. On information and belief, IPC Corp. and IPC Ltd. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., Elan Corp. v. IntelliPharmaCeutics Corp.* (D. Del. C.A. No. 07-603-SLR); *Purdue Pharma L.P. v. Intellipharmaceutics Corp.* (D. Del. C.A. No. 17-392-RGA); *Purdue Pharma L.P. v. Intellipharmaceutics Corp.* (D. Del. C.A. No. 18-404-RGA).

33. On information and belief, by virtue of, *inter alia*, Intellipharmaceutics' continuous and systematic contacts with Delaware, including but not limited to the above-described contacts, and the actions on behalf of IPC International and IPC Corp. in connection with NDA No. 209653 undertaken by their agent IPC Ltd., a Delaware corporation, this Court has personal jurisdiction over IPC International, IPC Corp. and IPC Ltd. These activities satisfy

due process and confer personal jurisdiction over IPC International, IPC Corp. and IPC Ltd. consistent with the Delaware long arm statute.

34. On information and belief, if NDA No. 209653 is approved, Defendants' NDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

35. This Court further has personal jurisdiction over Defendants by virtue of the fact that Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

36. Additionally, this Court may exercise jurisdiction over IPC International and/or IPC Corp. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) IPC International and IPC Corp. are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) IPC International and IPC Corp. have sufficient contacts with the United States as a whole, including but not limited to preparing and submitting NDA No. 209653 to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over IPC International and IPC Corp. satisfies due process.

THE PATENTS-IN-SUIT

THE '434 PATENT

37. Purdue and Rhodes are the lawful owners of all right, title and interest in the '434 patent, titled "PROCESS FOR PREPARING OXYCODONE COMPOSITIONS," including the right to sue and to recover for past infringement thereof. The '434 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '434 patent is attached hereto as Exhibit A, which was duly and legally issued on September 10, 2019, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

THE '109 PATENT

38. Grünenthal is the lawful owner of all right, title, and interest in the '109 patent, titled "ABUSE-PROOFED DOSAGE FORM," including the right to sue and to recover for past infringement thereof. The '109 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '109 patent, attached hereto as Exhibit B, was duly and legally issued on August 6, 2019, naming Johannes Bartholomäus and Heinrich Kugelmann as the inventors.

DEFENDANTS' NDA

39. On information and belief, on or about November 22, 2016, and after November 16, 2016, Defendants filed Defendants' NDA No. 209653 under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval to engage in the commercial manufacture, use, or sale of Defendants' NDA Products, products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

40. On information and belief, Defendants intend to use oxycodone hydrochloride ("HCl") as the active pharmaceutical ingredient ("API") in Defendants' NDA Products.

41. On information and belief, Defendants' NDA includes a "Paragraph IV" certification under 21 U.S.C. § 355(b)(3)(D) alleging that the patents-in-suit, each of which are listed in the FDA's Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of" the drug products described in Defendants' NDA.

42. In a letter dated March 12, 2020, addressed to Plaintiffs and received by Purdue Pharma on or about March 17, 2020, Defendants provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' NDA, Defendants' NDA Products, and the patents-in-suit, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("March 2020 Notice Letter").

43. Plaintiffs commenced this action within the 45-day period after receiving the March 2020 Notice Letter as described in 21 U.S.C. § 355(c)(3)(C).

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 10,407,434)

44. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

45. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 209653 to the FDA seeking approval of Defendants' NDA Products was an act of infringement of the '434 patent by Defendants.

46. On information and belief, the process for making the oxycodone HCl API that Defendants intend to use in Defendants' NDA Products is covered by one or more claims of

the ’434 patent, including but not limited to independent claim 1, which recites, *inter alia,* a process of purifying oxycodone free base or oxycodone HCl that contains 8α, 14-dihydroxy-7,8-dihydrocodeinone (“8α”) or HCl salt thereof, and various claims dependent therefrom.

47. If approved by the FDA, Defendants’ importation, offer for sale, sale, and/or use of the oxycodone HCl API in Defendants’ NDA Products will infringe one or more claims of the ’434 patent under 35 U.S.C. § 271(g).

48. Defendants’ NDA Products, or the use or manufacture thereof, are covered by one or more claims of the ’434 patent, including but not limited to dependent claim 20, which recites, *inter alia*, purified oxycodone HCl prepared according to the process recited in dependent claim 2, which recites, *inter alia,* the process of independent claim 1 as well as specific ratios of 8α or HCl salt thereof to oxycodone free base or oxycodone HCl at certain stages in the claimed process.

49. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of Defendants’ NDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’434 patent under 35 U.S.C. § 271(a)-(c).

50. Defendants’ NDA Products constitute a material part of the inventions covered by the claims of the ’434 patent.

51. On information and belief, Defendants have been aware of the existence of the ’434 patent, and have no reasonable basis for believing that Defendants’ NDA Products will not infringe the ’434 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

52. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '434 patent. Purdue and Rhodes do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 10,369,109)

53. Grünenthal and Purdue Pharma incorporate by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

54. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of NDA No. 209653 to the FDA seeking approval of Defendants' NDA Products was an act of infringement of the '109 patent by Defendants.

55. Defendants' NDA Products, or the use or manufacture thereof, are covered by one or more claims of the '109 patent, including but not limited to independent claim 1, which recites, *inter alia*, a tablet for oral administration with reduced potential for parenteral abuse, said tablet comprising: (a) one or more active ingredients having potential for abuse selected from the group consisting of (among others) oxycodone and pharmaceutically acceptable salts and solvates thereof; and (b) at least one viscosity-increasing agent in a quantity such that an aqueous extract of a total content of the tablet when comminuted and combined with 10 ml of water at 25° C forms a gel that can be drawn up into and injected back out of a hypodermic needle having a diameter of 0.9 mm, into a further quantity of water, wherein threads of the gel injected from said needle remain visible to the naked eye in said further quantity of water at 37° C.

56. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' NDA Products will infringe, contribute to

the infringement of, and/or induce the infringement of one or more claims of the '109 patent under 35 U.S.C. § 271(a)-(c).

57. Defendants' NDA Products constitute a material part of the inventions covered by the claims of the '109 patent.

58. On information and belief, Defendants have been aware of the existence of the '109 patent and have no reasonable basis for believing that Defendants' NDA Products will not infringe the '109 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

59. Unless Defendants are enjoined by the Court, Grünenthal and Purdue Pharma will be substantially and irreparably harmed by Defendants' infringement of the '109 patent. Grünenthal and Purdue Pharma do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendants have infringed one or more claims of each of the '434 and '109 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Defendants' NDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '434 and '109 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of NDA No. 209653 and Defendants' NDA Products, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), to be a date not earlier than the last date of expiration of the '434 and '109 patents, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of NDA No. 209653, including Defendants' NDA Products or any other drug product that infringes the '434 and '109 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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